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**Design of a Randomized Controlled Trial (RCT) Evaluating Outcome and Cost-effectiveness of a Local Case-Management Intervention of Patients Suffering from Chronic Obstructive Pulmonary Disease (COPD)**

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*Published in:*  
Value in Health

*DOI (link to publication from Publisher):*  
[10.1016/j.jval.2013.08.1564](https://doi.org/10.1016/j.jval.2013.08.1564)

*Publication date:*  
2013

*Document Version*  
Early version, also known as pre-print

[Link to publication from Aalborg University](#)

*Citation for published version (APA):*

Sørensen, S. S., Pedersen, K. M., & Ehlers, L. H. (2013). Design of a Randomized Controlled Trial (RCT) Evaluating Outcome and Cost-effectiveness of a Local Case-Management Intervention of Patients Suffering from Chronic Obstructive Pulmonary Disease (COPD). *Value in Health*, 16(7), A576.  
<https://doi.org/10.1016/j.jval.2013.08.1564>

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# DESIGN OF A RANDOMIZED CONTROLLED TRIAL (RCT) EVALUATING OUTCOME AND COST-EFFECTIVENESS OF A LOCAL CASE MANAGEMENT INTERVENTION OF PATIENTS SUFFERING FROM CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

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**OBJECTIVES:** In December 2011 the Danish Government issued a new plan of action for chronic disease management in the Danish counties and DKK 100 million were granted to set up new positions as case managers to help vulnerable elderly patients. No precise job description was provided, however, and the Danish counties request evidence for the effect of case management (CM). The aim of this study was to 1) design a job description for a case manager, and 2) design a RCT evaluating consequences and costs of providing local CM to patients with COPD.

**METHODS:** By use of the UK Medical Research Councils (MRC) framework for development of complex interventions, the design of the case manager job description and the RCT was determined through a systematic literature review, interviews with key persons and discussions in a specialist-comprised steering group.

**RESULTS:** CM was designed to encompass coordination of care, facilitation of relevant health- and social services and promotion of patient self-care through advocacy and education. The RCT was powered to detect the effect of CM on hospital admissions. Secondary measures include mortality, quality of life, self-care and cost-effectiveness of CM vs. usual care. 150 COPD patients are randomized into two groups after referral to pulmonary rehabilitation at the local rehabilitation center in Aalborg County, Denmark. The control group will receive usual care, whereas the interventional group will receive CM besides their usual care. Each patient is followed for 12 months. The questionnaires SF-12, EQ-5D, Sct. George-Respiratory-Questionnaire (SG-RQ) and The Patient-Activation-Measure (PAM-13) are completed at baseline and 12 months. Prospectively collected data from national population-based medical registries are used to estimate events and resource usage.

**CONCLUSION:** The study is expected to provide further insight to the future organization of CM, and if being cost-effective, the intervention could be applied to comparable healthcare settings.